



#11

PATENT
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Julio L. Pimentel)
Serial No.: 08/888,202) Examiner: Ungar
Filed: July 7, 1997) Art Unit: 1642
For: DECREASED FAT ABSORPTION WITH)
ANTI-LIPASE ANTIBODY)

" AFFIDAVIT UNDER 37 C.F.R. § 1.132

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

I, Richard Lee Atkinson, Jr., M.D., do hereby declare as follows:

1. I am Chief of the Section of Clinical Nutrition and Director of the Beers-Murphy Clinical Nutrition Center at the University of Wisconsin at Madison. I am a practicing clinical nutritionist.

2. My curriculum vitae is attached hereto as Exhibit A.

3. I am co-founder and President of the American Obesity Association, a non-profit organization, which pursues better quality of life for individuals with obesity and government recognition of obesity as a disease.

4. I am a former President of the North American Association for the Study of Obesity, an organization comprised of researchers, scientists, academicians, and clinicians who

share a common purpose to advance obesity research.

5. I am a former President of the American Society of Clinical Nutrition, an organization comprised of researchers, scientists, academicians, and clinicians who share a common purpose to advance research and education in clinical nutrition.

6. I have read and am familiar with the specification, including the claims, of U.S. Patent Application No. 08/888,202, filed July 7, 1997, by Julio L. Pimentel, entitled Decreased Fat Absorption With an Anti-Lipase Antibody.

7. Prior to being approached to review the specification, including the claims, of U.S. Patent Application No. 08/888,202, in connection with the preparation of this Affidavit, I had no dealings with the inventor, Julio L. Pimentel, with the assignee, XiMed Group PLC, or any of its predecessors in interest or legal representatives.

8. Obesity is a worldwide health problem that has reached epidemic proportions in the United States and globally according to the World Health Organization (WHO) [Reference: Preventing and managing the global epidemic of obesity: report of a WHO Consultation on Obesity. Geneva, 3-5 June, 1997. WHO/NUT/NCD98.1, Geneva, 1998.]

9. Obesity is predicted by reports of the United States Government and the WHO to increase dramatically the cost of health care in the United States and to seriously deplete healthcare budgets for underdeveloped countries by early in the 21st century. [References: 1) Preventing and managing the global epidemic of obesity: report of a WHO Consultation on Obesity. Geneva, 3-5 June, 1997. WHO/NUT/NCD98.1, Geneva, 1998., 2) Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults - The Evidence Report. Obesity Research 6(Suppl 2):51S-209S, 1998.]

10. Obesity was identified as a serious health concern by Aristotle and by physicians and scientists ever since then.

11. Obesity is a cause or major contributing factor to many life threatening human illnesses or conditions, including diabetes mellitus, hypertension, dyslipidemia, atherosclerosis, cardiac disease, cerebrovascular accidents, sleep apnea, gallbladder disease, cancer, and gout, among others.

12. According to the National Academy of Sciences, obesity is the second leading cause of preventable deaths in the United States. [Reference: Thomas PR, ed. 1995. Weighing the Options. Criteria for Evaluating Weight-Management Programs. Washington: National Academy Press.]

13. Many drugs that were developed and marketed have not been successful or have caused undesirable side effects and have been removed from the market, or their use abandoned by physicians, including such drugs as chlorphentermine, dexamphetamine, dexfenfluramine, fenfluramine, Mazinor^R, methamphetamine, and phenmetrazine. [Reference: Atkinson RL. Use of drugs in the treatment of obesity. Annual Review of Nutrition 17:383-403, 1997.]

14. An effective method of reducing obesity would be to inhibit pancreatic lipase in the gastro-intestinal tract, thus leading to the malabsorption of a portion of dietary fat.

15. Prior to reading the specification, including the claims, of U.S. Patent Application No. 08/888,202, I was skeptical that antibodies introduced into the small intestine, i.e. into the gastro-intestinal tract, in humans and other non-ruminant mammals, would have any activity past the newborn period.

17. My skepticism as to the possibility of introducing antibodies into the gastro-intestinal tract in post-newborn humans and other non-ruminant mammals for the purpose of inhibiting pancreatic lipase was due in part to the fact that the large amount of gastric acid and protein digestive enzymes in the human digestive system would be expected to destroy any

antibodies before they could reach the point in the duodenum where pancreatic lipase enters.

18. The claimed invention of U.S. Patent Application No. 08/888,202 requires the antibodies to reach the duodenum of the gastro-intestinal tract (GI tract) and still be active to inhibit pancreatic lipase.

19. One of the types of lipase it is desirable to inhibit, in order to assist in combating obesity, is pancreatic lipase, the enzyme responsible for digestion of most of the fat in the human GI tract.

20. That antibodies can reach the duodenum and still be active to inhibit pancreatic lipase was not obvious to me as of July 7, 1997.

21. Although initial positive pancreatic lipase blocking results have been achieved using tetrahydrolipstatin (generic name: orlistat, trade name: Xenical^R), which is not systemically absorbed, Xenical^R is an entirely different molecule that is unrelated to human or animal antibodies. Also, it is possible that individuals might become allergic to Xenical^R, which would prevent its use in certain groups of prospective obese patients. [Reference: 1) Package insert, Xenical^R, Hoffman-LaRoche, Inc., 2) James WP, Avenell A, Broom J, Whitehead J. A one year trial

to assess the value of orlistat in the management of obesity.
Int J Obesity 21(Suppl 3):S24-S30, 1997.]

22. Because of the possibility that allergenicity might prevent the use of Xenical^R in certain groups of prospective obese patients, it is my opinion that there remains a need for alternate methods of inhibiting pancreatic lipase in the gastrointestinal tract, and this need has not been satisfied by Xenical^R.

22. I have reviewed the Office Actions mailed August 18, 1998 and February 3, 1999, and have read each of the references cited by the Examiner.

23. In my opinion, based on the teachings of the references cited in the Examiner's rejections under 35 U.S.C. § 103 in the Office Actions mailed August 18, 1998 and February 3, 1999, namely item number 9 of the August 18, 1998 Office Action and item numbers 5, 7 and 8 of the February 3, 1999 Office Action, the references do not render the claimed invention obvious because the references relate to non-analogous art from one another and would not be combined in the manner proposed by the Examiner.

24. In my opinion, based on the teachings of the references cited in the Examiner's rejections under 35 U.S.C. § 103 in the

Office Actions mailed August 18, 1998 and February 3, 1999, namely item number 9 of the August 18, 1998 Office Action and item numbers 5, 7 and 8 of the February 3, 1999 Office Action, the references do not render the claimed invention obvious because the references relate to non-analogous art from the claimed invention and therefore would not be looked to by those skilled in the art seeking to solve the problem of inhibiting lipase in the gastro-intestinal tract.

25. Based upon my review of the Hadvary et al. patent, U.S. Patent No. 4,598,089, it is my opinion that the Hadvary patent is in the biochemistry art, it does not concern antibodies, and the patent only shows one very different treatment for obesity than the method claimed in U.S. Patent Application No. 08/888,202.

26. Based upon my review of the Ohkaru et al. reference, (Clin. Chim. Acta (1989) 182:295-300), it is my opinion that the Ohkaru et al. reference is in the art of clinical pathology, which is an art non-analogous to the biochemistry art of the Hadvary et al. patent, and because the Ohkaru et al. reference is in clinical pathology, as opposed to biochemistry, one would not look to Ohkaru et al., either alone or in combination with the other references cited by the Examiner, to modify or add to Hadvary et al., U.S. Patent No. 4,598,089, to arrive at the method claimed in U.S. Patent Application No. 08/888,202.

27. Based upon my review of the Ohkaru et al. reference, it is my opinion that the Ohkaru et al. reference relates to the use of monoclonal antibodies against pancreatic lipase that enabled development of a clinical assay for the measurement of pancreatic lipase that had leaked into the bloodstream from damaged cells in individuals with pancreatitis, which is not analogous to the art of the claims of U.S. Patent Application No. 08/888,202, which require the delivery of antibodies through the digestive system and into the gastro-intestinal tract to inhibit lipase.

28. Based upon my review of the Kajita et al. reference, JP 02150294, it is my opinion that the Kajita et al. reference is in the art of clinical pathology, which is an art non-analogous to the biochemistry art of the Hadvary et al. patent, and because the Kajita et al. reference is in clinical pathology, as opposed to biochemistry, one would not look to the Kajita et al. reference, either alone or in combination with the other references cited by the examiner, to modify or add to Hadvary et al., U.S. Patent No. 4,598,089, to arrive at the method claimed in U.S. Patent Application No. 08/888,202.

29. Based upon my review of the Kajita et al. reference, it is my opinion that the Kajita et al. reference does not discuss obesity or nutrition, but instead relates to the use of monoclonal antibodies directed against pancreatic lipase that enabled development of a clinical assay for the diagnosis of the

presence of pancreatic lipase in the bloodstream in individuals with pancreatitis, and the Kajita et al. is not analogous to the art of the claims of U.S. Patent Application No. 08/888,202, which require the delivery of antibodies through the digestive system and into the gastro-intestinal tract to inhibit lipase.

30. Based upon my review of the Moloney reference (Livestock Production Science, 1995, 42:239-245), it is my opinion that the Moloney reference is directed to the unrelated problem of making antibodies to insulin and injecting antibodies into the blood stream, and the Moloney reference would not be looked to by one trying to solve the problem solved by the claims of U.S. Patent Application No. 08/888,202, which require the oral delivery of antibodies through the digestive system and into the gastro-intestinal tract to inhibit lipase. These are fundamentally different because antibodies injected into the bloodstream would not be immediately destroyed, whereas I would have expected that antibodies taken by mouth would be immediately destroyed in the stomach or upper duodenum. In addition, since Moloney is directed to those interested in destroying fat cells, as opposed to inhibiting pancreatic lipase, thus one would not be motivated to look to the Moloney reference, either alone or in combination with the other references cited by the examiner, to modify or add to Hadvary et al., U.S. Patent No. 4,598,089, to arrive at the method claimed in U.S. Patent Application No. 08/888,202.

31. Based upon my review of the Flint reference, Proceedings of the Nutrition Society, 1992, 51:433-439), it is my opinion that the Flint reference is directed to the unrelated problem of destroying fat cells with antibodies by injecting the antibodies into humans in order to cause the fat cells to rupture and release all the fat they contain. This theoretical treatment, in my opinion, is entirely unrelated and non-analogous to the use of antibodies against pancreatic lipase, and the Flint reference would not be looked to by one trying to solve the problem solved by the claims of U.S. Patent Application No. 08/888,202, which require the oral delivery of antibodies through the digestive system and into the gastro-intestinal tract to inhibit lipase. Furthermore, one would not look to the Flint reference, either alone or in combination with the other references cited by the examiner, to modify or add to Hadvary et al., U.S. Patent No. 4,598,089, to arrive at the method claimed in U.S. Patent Application No. 08/888,202.

32. Based upon my review of the Coleman patent, U.S. Patent No. 5,585,098, this patent is totally unrelated to treating obesity, but rather, is concerned with treating a disease in ruminant animals, specifically to the use of antibodies against some of the pathogens that cause mastitis in cattle. This is not analogous to the use of antibodies against pancreatic lipase in the gastro-intestinal tract of non-ruminant mammals. One would not look to the Coleman patent, either alone or in combination

with the other references cited by the examiner, to modify or add to Hadvary et al., U.S. Patent No. 4,598,089, to arrive at the method claimed in U.S. Patent Application No. 08/888,202.

33. Based upon my review of the Tokoro reference, U.S. Patent No. 5,080,895, it is my opinion that this patent is totally unrelated to treating obesity, but rather, is concerned with preventing or treating an intestinal infectious disease in a neonatal mammal caused by a pathogenic organism which has not acquired resistance to a specific antibody containing substance. This is not analogous to the use of antibodies against pancreatic lipase in the gastrointestinal tract. Further, one would not look to the Tokoro patent, either alone or in combination with the other references cited by the Examiner (such as the Kajita et al. reference, JP 02150294, which in my opinion is in the art of clinical pathology, an art non-analogous to the biochemistry art of the Hadvary et al. patent) to modify or add to the Hadvary et al. reference to arrive at the method claimed in U.S. Patent Application No. 08/888,202.

34. Based upon my review of the Murase et al. reference, Atherosclerosis, 1981, 39:293-300), it is my opinion that the Murase et al. reference is in the art of clinical pathology, which is an art non-analogous to the biochemistry art of the Hadvary et al patent. Specifically, Murase et al. relates to the use, by injection into the jugular vein of rats, of an antibody

prepared specifically against the enzyme hepatic lipase in order to investigate the role of this enzyme in lipoprotein metabolism. One searching for an obesity treatment would not turn to Murase et al. to find any suggestion as to a solution involving the oral introduction of anti-lipase antibodies into non-ruminant mammals, even if that person were aware of the other references cited by the Examiner. As such, one would not look to the Murase et al. reference, either alone or in combination with the other references cited by the Examiner, to modify or add to Hadvary et al. to arrive at the method claimed in U.S. Patent Application No. 08/888,202.

I affirm that the statements above are true to the best of my knowledge and belief, and I am aware that any false statements herein may subject me to penalties for perjury and may jeopardize the validity of any patent or patents that may issue on the subject patent application.

Dated: August 6, 1999

Richard L. Atkinson, Jr.
Richard Lee Atkinson, Jr., M.D.

Signed before me this 6th day
of August, 1999.

John L. Steinhilber
Notary Public

A

February, 1999

CURRICULUM VITAE

RICHARD LEE ATKINSON, JR., M.D.

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PROFESSIONAL APPOINTMENTS:

Professor of Medicine and Nutritional Sciences; Director, Beers-Murphy Clinical Nutrition Center; Chief, Section of Clinical Nutrition; University of Wisconsin; 1993 - Present

Professor of Internal Medicine; Chief, Division of Clinical Nutrition; Eastern Virginia Medical School; Norfolk, Virginia; 1987 - 1993

Associate Chief of Staff for Research and Development; Chief, Medical Research Service; VA Medical Center; Hampton, Virginia; 1987 - 1993

Adjunct Professor, Graduate College, Hampton University, Hampton, VA; 1992 - 1993

Associate Professor of Internal Medicine; Director, Clinical Nutrition Center, School of Medicine, University of California at Davis; Davis, California; 1983 - 1987

Assistant Professor of Internal Medicine; Director, Clinical Nutrition Center, University of Virginia School of Medicine, Charlottesville, Virginia, 1977 - 1983

Adjunct Lecturer in Health Studies; Pennsylvania State University, State College, Pennsylvania, 1978 - 1980

Adjunct Assistant Professor of Medicine; School of Medicine; University of California, Los Angeles, California, 1976 - 1977

Liaison Endocrinologist (Clinical Instructor), Vanderbilt University Medical Center, Nashville, Tennessee, 1973 - 1974

Chief, Department of Medicine; U.S. Army Hospital; Fort Campbell, Kentucky, 1973 - 1974

EDUCATION:

College: B.A., Virginia Military Institute, Lexington, Virginia, 1960 -1964

Medical School: M.D., Medical College of Virginia, Richmond, Virginia, 1964 -1968

Internship: Medical College of Virginia, Richmond, Virginia (straight medicine), 1968-1969

Residency: Harbor General Hospital, Torrance, California (Medicine), 1969-1970

Fellowship: Walter Reed General Hospital, Washington, DC
(Endocrinology-Metabolism), 1970-1972

Harbor General Hospital, Torrance, California (Endocrinology-Metabolism),
Research Fellowship, National Institute of Child Health and Human
Development, 1974-1976

Harbor General Hospital, Torrance, California, Chief Resident in
Endocrinology, 1976-1977

BOARD CERTIFICATION:

Diplomate, American Board of Internal Medicine, June, 1972

Diplomate, Endocrinology and Metabolism, American Board of Internal Medicine, October, 1973

Diplomate, American Board of Nutrition, May, 1985

STATE CERTIFICATION:

Virginia: 1968 #19193
California: 1969 #C31542
Wisconsin: 1994 #35119

SOCIETY MEMBERSHIPS:

Fellow, American College of Physicians
Member, American Diabetes Association
Member, American Society of Bariatric Physicians
Member, American Society for Nutritional Sciences
Member, American Society for Clinical Nutrition
Member, American Society for Parenteral and Enteral Nutrition
Member, Endocrine Society
Member, North American Association for the Study of Obesity

ACTIVITIES AND HONORS:

Medical School:

Vice-President of the Student Body, School of Medicine, 1967 - 1968

Chairman of the Honor Council, 1967 - 1968

Vice-President, Alpha Sigma Xi Honorary Leadership Society, 1967 - 1968

Academic Committees:

Hospital Executive Committee, U.S. Army Hospital, Ft. Campbell, KY, 1973 - 1974

Department of Medicine Executive Committee, Harbor General Hospital, Torrance, CA, 1976 - 1977

Executive Committee, Diabetes Research & Training Center, University of Virginia Medical School, 1981 - 1983

Advisory Committee, Diabetes Research and Training Center, University of Virginia Medical School, **Chairman**, 1981 - 1983

Executive Committee, University of California, Davis, School of Medicine, 1985 - 1987

Vice Chairman of the Faculty, School of Medicine, University of California, Davis, 1985 - 1987

Medical Student Promotions Committee, University of California, Davis, **Chairman**, 1985 - 1987

Admissions Committee, Graduate Group in Nutrition, University of California, Davis, 1985 - 1987

Executive Committee, Clinical Nutrition Research Unit, University of California, Davis, 1985 - 1987

Director, Metabolic Core Laboratory, Clinical Nutrition Research Unit, University of California, Davis, 1985 - 1987

Research and Development Committee, VA Medical Center, Hampton, VA, **Secretary**, 1987 - 1993

Nutrition Committee, VA Medical Center, Hampton, VA, 1987 - 1989

Research Committee, Eastern Virginia Medical School, Norfolk, VA, 1987 - 1990

Committee on Committees, Eastern Virginia Medical School, Norfolk, VA, 1991 - 1993

Ethics Committee, VA Medical Center, Hampton, VA, 1993 - 1993

Dietary Committee, University of Wisconsin Hospital, 1994 -Present

Academic Committees (continued):

Space Committee, Dept. of Nutritional Sciences, University of Wisconsin, 1994- Present

Research Seminar Committee, Dept. of Nutritional Sciences, University of Wisconsin, 1994- Present

UW Foundation Committee, University of Wisconsin Hospital, 1994 - Present

Offices and Committees of Professional and Health Related Societies:

American Diabetes Association: **Vice President**, Virginia Affiliate, 1982 - 1983

American Institute of Biological Sciences, Scientific Peer Advisory and Review Services: Panel on US Army Research Institute of Environmental Medicine Field Ration Testing, 1998 - Present

American Institute of Nutrition (American Society for Nutritional Sciences)/American Society for Clinical Nutrition:

AIN/ASCN Membership Committee, 1986 - 1990; **Chairman**, 1989 - 1990

AIN/ASCN Public Information Committee, 1988 - 1990

ASCN Nominations Committee, 1990

Ad hoc Search Committee for the ASCN Executive Officer, **Chairman**, 1993

Ad hoc Committee on a Unifying Nutrition Certification Exam, **Chairman**, 1993

ASCN **Vice-President Elect**, 1992 - 1993

Vice-President, 1993 - 1994

President, 1994 - 1995

ASCN Nominations Committee, 1997

American Obesity Association: **Co-founder and President**, 1995 - Present

North American Association for the Study of Obesity:

1989 Annual Meeting Organizing Committee, **Chairman**

Vice President, 1988 - 1989

President-Elect, 1989 - 1990

President, 1990 - 1991

Education Committee, **Chair**, 1990 - 1992

Nominating Committee, 1992 (**Chair**); 1994

National Academy of Sciences, National Institutes of Health, Department of Health and Human Services, Department of Veterans Affairs, and World Health Organization Committees and Activities:

NIH Site Visit Committee, Program Project, Baylor University, Houston, TX, February, 1983.

NIH Site Review Committee, University of Alabama Medical School Multipurpose Arthritis Center Application, Birmingham, Alabama, January, 1984.

NIH Site Review Committee, Clinical Nutrition Research Center, Vanderbilt University, Nashville, Tennessee, April, 1984.

NIH Site Review Committee, Program Project, University of Pittsburgh, Pittsburgh, Pennsylvania, June, 1986.

National Academy of Sciences, National Institutes of Health, Department of Health and Human Services, Department of Veterans Affairs, and World Health Organization Committees and Activities (continued):

NIH Behavioral Neurobiology Study Section, Ad Hoc Reviewer, June, 1987.

Veterans Affairs Central Office, Merit Review Appeals Committee, 1987 - 1990

National Academy of Sciences, Food and Nutrition Board, Committee on Military Nutrition Research, 1989 - 1995

NIH Nutrition Study Section, Special Reviewer, November, 1989; February, 1991.

NIH, Planning Committee, Consensus Development Conference: Surgery for Severe Obesity, 1990 - 1991

NIH, Special Study Section for Obesity Research Centers, July, 1990

NIH, NIDDK: National Task Force on Prevention and Treatment of Obesity, 1991 - 1995

NIH, NIDDK Advisory Group on Clinical Nutrition Research Centers, 1991

NIH, Planning Committee, Technology Assessment Conference: Health Effects of Voluntary Weight Loss Efforts, 1991 - 1992

NIH Nutrition Study Section, Member, 1991 - 1995; **Chairman** 1993 - 1995

Veterans Affairs Central Office, Research Equipment Committee, 1992 - 1993

Health and Human Services, Office of Disease Prevention and Health Promotion, Nutrition Policy Staff Working Group on Healthy Weights, 1992 - 1994

Food and Drug Administration, Consultant, 1994 - 1995

National Academy of Sciences: Review Coordinator, *Report on Guidelines for Weight Control Programs*, 1994 - 1995

Health and Human Services, Office of Disease Prevention and Health Promotion: Senior Editorial Advisor, *Surgeon General's Report on Dietary Fat and Health*, 1994 - 1998

World Health Organization, Expert peer reviewer for *Obesity: Preventing and Managing the Global Epidemic - Report of a WHO Consultation on Obesity (WHO/NUT/98.1)*, 1997

NIH, Member, Advisory Committee: Working Group on Human Subjects (High Volume), 1998 - Present

National Institute on Aging, Member, Caloric Restriction Clinical Implications Advisory Group, 1998 - Present

MEETINGS ORGANIZED:

Chairman, Organizing Committee, Annual Meeting of the North American Association for the Study of Obesity, Bethesda, Maryland, September 13-16, 1989.

Chairman, Program Committee, American Institute of Nutrition Public Information Committee Symposium on Obesity, Annual Meeting: Federation of American Societies for Experimental Biology, Washington, D.C., April, 1990.

Chairman, Program Committee, Symposium on Very Low Calorie Diets, Satellite Symposium to the Sixth International Congress on Obesity, Kyoto, Japan, October 19-20, 1990.

Chairman, Program Committee, Symposium on Obesity, Congress of the Latin American Nutrition Society, San Juan, Puerto Rico, September 22-26, 1991.

Chairman, Organizing Committee, North American Association for the Study of Obesity Continuing Medical Education Conference, Atlanta, GA, November 30-December 1, 1991.

Chairman, Organizing Committee, Joint 9th Annual Virginia Nutrition Conference and North American Association for the Study of Obesity Continuing Medical Education Conference, Hampton, VA, March 5-7, 1992

Chairman, Organizing Committee, NIH Workshop: "Pharmacologic Treatment of Obesity", Atlanta, GA, September 1, 1992

Chairman, Organizing Committee, FASEB Symposium, "Controversies in Obesity," Experimental Biology Annual Meeting, New Orleans, LA, March 30, 1993

Chairman, Organizing Committee, American Society for Clinical Nutrition CME Course, "Nutrition and Cardiovascular Risk," Williamsburg, March 3-5, 1994

Co-Chairman, Organizing Committee, Satellite Symposium on Pharmacologic Treatment of Obesity, International Congress on Obesity, St. Adele, Quebec, Canada, August 18-20, 1994

Chairman, Planning Committee, First Annual Wisconsin Nutrition Continuing Education Conference, "Obesity Update '96," Madison, March 31-April 1, 1996.

MEDICAL JOURNAL ACTIVITIES:

Editorial Activities:

Contributing Editor - Nutrition Reviews, 1984 - 1992

Medical Advisory Board - Obesity Update, 1986 - 1993

Editorial Board - Journal of Nutrition, 1988 - 1992

Editorial Board - International Journal of Obesity, 1991 - present

Guest Editor, Volume 56 Supplement: "Very-Low-Calorie Diets", American Journal of Clinical Nutrition, 1992

Editorial Board, Section Editor, Obesity Research, 1992 - Present

Editorial Board, Weight Control Digest, 1997 - Present

Editorial Board, Diabetes Technology & Therapeutics, 1998 - Present

MEDICAL JOURNAL ACTIVITIES (continued):

Reviewer for: American Journal of Clinical Nutrition
American Journal of Physiology
American Journal of Public Health
Diabetes
Diabetes Care
Gastroenterology
International Journal of Obesity
Journal of the American Dietetic Association
Journal of Clinical Endocrinology and Metabolism
Journal of Clinical Investigation
Journal of Nutrition
New England Journal of Medicine
Physiology and Behavior
Science

HISTORY OF GRANT SUPPORT: (* Principal Investigator)

- * "Effects of Exercise on Weight Loss and Metabolism in Obesity," Biomedical Research Support Subgrant, University of Virginia School of Medicine, 2/15/78 to 4/1/79, \$5,000.
- * "Metabolic Effects of Dieting and Weight Loss," Diabetes Research and Training Center Grant," NIH P30 AM17042, 6/1/77 to 8/31/79, \$53,159.
- * "Role of the Ileum in Regulating Food Intake in Rats," Diabetes Research and Training Center Grant," NIH P60 AM22125, 9/1/79 to 8/31/80, \$10,500.
- * "Humoral Mechanisms of Satiety," DHHS-NIADDKD 2 RO1 AM26225, 4/1/80 to 11/30/83, \$101,940.
- * "Humoral Mechanisms of Satiety," DHHS-NIADDKD 2 RO1 AM26225-S, (supplement) 1/1/81 to 11/30/83, \$15,201.
- * "Treatment of Obese Non-Insulin Dependent Diabetics with Home Glucose Monitoring and a Very Low Calorie Diet," Cambridge Quest Foundation, 5/1/82 to 4/30/84, \$31,500.
- * "Effects of Naltrexone on Body Weight, Metabolism, and Hormone Levels," DuPont Pharmaceuticals, 12/1/82 to 11/30/83, \$152,499.
- * "Zinc and Copper Metabolism in Obese Zucker Rats," Mead Johnson, Inc., 1/1/84 to 11/31/84, \$6,480.
- * "Endocrine, Metabolic, and Cardiovascular Effects of a Very Low Calorie Diet and Exercise," California Trim Plan, 3/1/84 to 2/28/85, \$30,000.
- * "Use of a Fiber Supplement for Weight Reduction," A. H. Robbins, 2/1/84 to 1/31/87, \$250,000.

HISTORY OF GRANT SUPPORT: (* Principal Investigator)

- * "Hormonal, Metabolic, and Behavioral Effects of Medium Chain Triglycerides in Obese Humans," Mead Johnson, Inc., 9/1/84-12/31/87, \$80,000.

"Metabolic Core Laboratory, Core Director, Clinical Nutrition Research Unit," NIH 1 P30 AM35747 - 01, September 1, 1985 - August 31, 1990, \$41,453

"Postprandial Changes in Plasma Lipids," Pilot Project, Clinical Nutrition Research Unit, NIH 1 P30 AM35747 - 01, September 1, 1985 - August 31, 1986, \$9847, Co-investigator with P.A. Davis and B.O Schneeman.
- * "Intestinal Mechanisms of Body Weight Regulation", VA Research Advisory Group Program, 2/1/88-9/30/88, \$69,000.
- * "Intestinal Mechanisms of Body Weight Regulation", VA Merit Review, 10/1/88-9/30/91, \$207,195.
- * "Molecular Mechanisms of Alterations in Energy Expenditure", Biomedical Research Support Grant, Eastern Virginia Medical School, Sponsor for Carol N. Boozer, Sc.D., Postdoctoral Fellow, 7/1/88-6/30/89, \$2500.
- * "Mechanisms of Weight Loss After Intestinal Surgery for Obesity", Biomedical Research Support Grant, Eastern Virginia Medical School, Sponsor for Patricia S. Choban, M.D., 7/1/88-6/30/89, \$2500.
- * "Glucose and Energy Metabolism with Acarbose Treatment", Miles Laboratories, 1/1/90-6/30/91, \$31,000.
- * "Evaluation of Anorectic Activity of Phenylpropanolamine Caplets in the Treatment of Obesity," Thompson Medical Company, 1/1/90-12/31/91, \$104,000.

"Fuel Oxidation and Diet-Induced Obesity," Jeffress Foundation, 1/1/91-12/31/92. Principal Investigator - Carol N. Boozer, D.Sc., \$41,400,
- * "Lovan: Effect on Patient Adherence to a Diet Program and Evaluation of Responders and Non-responders to Determine Subtypes of Obesity," Eli Lilly Company, 12/1/91-11/30/94, \$564,000.
- * "Mechanisms of Weight Loss with Obesity Surgery," NIH RO1-DK43250, 9/1/91-8/31/95, \$281,484.
- * Beers-Murphy Clinical Nutrition Center, University of Wisconsin, Madison, 12/1/93-Present, \$1,855,000.
- * Regulation of Energy Balance: Intestinal Mechanisms; NIH RO1 DK44397, 7/1/97-6/30/00, \$436,974.
- * "Animal Models of Virus Induced Obesity," NIH RO1 DK52227, 9/30/97-9/29/00, \$444,582
- * "The Effects of Conjugated Linoleic Acid in Obese Humans," Natural Nutrition, Inc., 9/15/97-9/14/99, \$175,000.

HISTORY OF GRANT SUPPORT: (* Principal Investigator)

- * A Comparison of the Long Term Efficacy of Self-Help Weight Loss Versus a Commercial Weight Loss Program. Weight Watchers Foundation, 4/15/98-10/14/00, \$114,363.
- * Comparison of the prevalence of cardiac valvular abnormalities in patients treated with the combination fenfluramine and phentermine for at least three consecutive months versus untreated controls, as assessed by echocardiogram. Wyeth-Ayerst Laboratories, 4/20/98-4/19/99, Approximately \$60,000.
- * Treatment of Obesity with Phentermine and Fluoxetine, Eli Lilly, 4/30/98-4/29/99, \$19,396
- * Comparison of echocardiograms and clinical outcomes of patients previously treated with phentermine-fenfluramine vs phentermine-fluoxetine. Eli Lilly, 6/30/98-6/29/99, \$93,563.

Non-invasive measurement of energy expenditure in man, NIH R01-DK30031, 4/1/95-3/31/00, \$470,953 (PI: DA Schoeller)

PENDING GRANT SUPPORT: (* Principal Investigator)

- * Use of Conjugated Linoleic Acid in Dairy Products to Prevent Weight Regain or Alter Body Composition Following a Very Low Calorie Diet in Obese People; Dannone, Inc., 4/1/99-10/31/00, \$215,000
- Non-human Primate Model for Human Adenovirus Induced Obesity, NIH, 12/1/99-11/30/02, \$199,998 (PI: NV Dhurandhar)
- Obesity and Fibromyalgia: Symptom Expression and Physiology, NIH, 3/1/99-2/28/2003, \$311,793 (PI: D Muller)
- * Adenovirus & Human Obesity-Longitudinal and Twin Studies, NIH, 7/1/99-6/30/04, \$1,100,000.
 - * University of Wisconsin Clinical Nutrition Research Unit (CNRU), NIH, 7/1/99-6/30/04, \$3,750,000

MILITARY SERVICE:

Endocrine Fellow, Walter Reed Army Hospital, Washington, D.C., 1970 - 1972

Division Surgeon, 101st Airborne Division, Fort Campbell, KY, 1973 - 1974

Chief, Dept. of Medicine, U.S. Army Hospital, Fort Campbell, KY, 1973-1974

Army Commendation Medal, Fort Campbell, KY, 1974

INVITED LECTURES: (over 250 invited national and international lectures)

1997 lectures (outside Madison, WI):

American Diabetes Association Annual CME Course
Rivendell Psychiatric Hosp, Bowling Green, KY
University of Medicine and Dentistry of New Jersey, New Brunswick, NJ
University of North Carolina, Chapel Hill, NC
American Society of Bariatric Physicians CME Course, New Orleans, LA
American Association of Clinical Endocrinologists CME Course, Philadelphia, PA
American College of Physicians CME Lecture, Washington, DC
Health Learning Systems, Tucson, AZ
Northeastern Ohio Universities, Akron, OH
Endocrine Club, Washington, DC
XI Annual Congress on Metabolism and Nutrition Support, Medellin, Columbia
Grant Hospital CME lecture, Columbus, OH
Endocrine Society Annual Meeting, Minneapolis, MN
Hennepin County Hospital, Minneapolis, MN
16th International Congress of Nutrition, Montreal, Canada
American Association of Clinical Endocrinologists, Montreal, Canada
Fox Valley Medical Society, Door County, WI
Federal Trade Commission, Washington, DC
American Society of Bariatric Physicians Annual Meeting, New Orleans, LA
Interstate Postgraduate Medical Society Annual Meeting, Las Vegas, NV
Institute of Nutrition, University of North Carolina, Chapel Hill, CME Conference
North American Association for the Study of Obesity Annual CME Course, Cancun, Mexico

1998 lectures (outside Madison, WI):

Novartis Corporation, Basel, Switzerland
American Society for Parenteral and Enteral Nutrition Annual Meeting, Orlando, FL
Janssen-Cilag/Ortho McNeil, International Top Opinion Leader Seminar, London, England
American Diabetes Association Annual CME Course, San Francisco, CA
Academy of Medicine, Milwaukee, WI
Trout Lecture, Michigan State University, Lansing, MI
University of Kentucky, Lexington, KY
Law Journal Seminar, New York, NY
Gunderson Clinic, LaCrosse, WI
Endocrine Society Annual Meeting, New Orleans, LA
Obesity Research Network CME Course, New Orleans, LA
NIH International Symposium on Obesity, Charleston, SC
University of Minnesota Medical Grand Rounds, Minneapolis, MN
St. Louis University Medical School, CME Course, St. Louis, MO
Wisconsin Academy of Family Physicians, CME Course, Waukesha, WI
Zeneca Corporation, Brugge, Belgium
Cornell University Medical School, Memorial Sloan-Kettering Hospital, New York, NY

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B. ABSTRACTS: Over 130 abstracts published or in press.